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Inventor: Andrzej CZERNECKI et al.

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REMARKS

Reconsideration of this application is respectfully requested in view of the following remarks.

Claims 3, 4, 8, 10, and 12-19 were pending in this application. In this Request for Reconsideration, Applicants have not amended, canceled, or added any claims. Accordingly, claims 3, 4, 8, 10, and 12-19 will remain pending in this application upon entry of this Request. Applicants have provided the above listing of the currently pending claims for the Examiner's convenience.

In the final Office Action mailed January 22, 2009, claims 3-4, 8, 10, and 12-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0039387 to Rutynowski et al. ("Rutynowski") in view of U.S. Patent No. 7,087,068 to Marshall et al. ("Marshall"). Applicants respectfully traverse those rejections.

At page 7 of the Office Action, the Examiner asserted that the feature upon which Applicants' patentability arguments rely is not recited in the pending claims. The Examiner described that feature as "a device in which the puncture force is adjusted without adjusting the drive spring." Applicants respectfully submit, however, that this feature is recited in the pending claims.

For example, independent claim 3 recites a first distance in which the drive spring is held between the face of the push element and the piston in a first stable position, a second distance at which the puncturing force adjusting member is spaced apart from the piston in the first stable position, and a third distance in which the drive spring is compressed between the face of the

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push element and the piston at the operational position at which the puncturing force adjusting member presses the piston. Figure 4 of the present application illustrates the first and second distances as marked below:

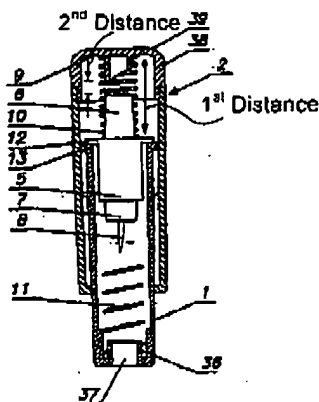
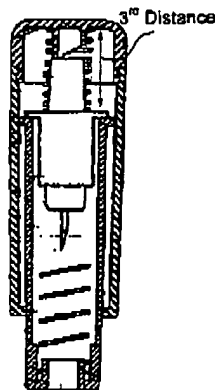


Fig. 4

The figure below illustrates the recited third distance, with the device in an operational position with the puncturing force adjusting member pressing on the piston (before breaking wings 12):



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Claim 3 further recites that the puncturing force adjusting member changes the second distance without changing the first distance. Thus, referring to the figures above, the drive spring 10, which occupies the first distance, is not adjusted as the second distance is adjusted. In other words, the puncturing force adjusting member 38 changes the second distance so as to adjust the third distance within which the drive spring 10 is compressed between the face of the push element 2 and the piston 5 at the operational position where the puncturing force adjusting member presses 38 the piston 5, *but does not change the first distance whatsoever*. Changing the second distance causes a change in the puncturing force because that puncturing force is dependent upon the third distance, which is the difference between the first distance and the second distance. But, again, as claim 3 recites, when the puncturing force adjustment member changes the second distance, it does not change the first distance. The other independent claims 4 and 12 similarly recite that feature.

In contrast, nowhere does Marshall disclose that the puncture force is adjusted without adjusting the drive spring 38. As set forth in the Remarks of the Amendment filed October 8, 2008 (which are incorporated by reference herein), in Marshall, there is no drive spring having a length equal to the first distance (distance d_1 noted by the Examiner) and positioned between the face of a push element and the piston, as recited in claims 3, 4, and 12. Accordingly, Marshall could not possibly teach or suggest the present invention's patentable feature of adjusting puncture force without adjusting the drive spring. Moreover, in Marshall, the distance within which drive spring 38 is compressed *is changed* when the force adjuster 39 is changed. (See, e.g., column 4, lines 12-22.)

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Applicants also specifically traverse the Examiner's "design choice" rationale for modifying Rutynowski by Marshall at page 6 of the Office Action. The Examiner suggested that using a longer spring in the combined device would enable the adjusting of the puncturing force over a larger range of possible puncturing forces. In Rutynowski, however, the length of drive spring 10 before the device is used is irrelevant to the puncturing force because the puncturing force is determined by the distance within which the drive spring 10 is compressed when the front 9 of button 2 rests on pusher 6 of piston 5 (paragraph [0013]), just before the wings 12 are broken. Merely changing the distance in which drive spring 10 is compressed would not adjust the puncturing force when the button 2 pushes on the pusher 6 and breaks the wings 12, since in operation the drive spring would always be compressed the same distance, regardless of the distance within which it was compressed before the button 2 was pushed. Thus, initially using a shorter or longer spring *would not* enable the adjusting of the puncturing force at all, let alone over a larger range of possible puncturing forces.

In addition, Rutynowski, in fact, teaches away from introducing the puncturing force adjusting means of Marshall to the Rutynowski device because of the use of the breakable wings 12. Indeed, the means for adjusting puncturing force taught by Marshall would clearly make the Rutynowski device inoperable and ineffective by risking the breaking of wings 12 before use of the device. In other words, decreasing the distance within which the drive spring 10 of Rutynowski is compressed would increase the force on the wings 12, potentially breaking them and releasing the piston 5 unintentionally. Thus, contrary to the Examiner's assertions, the

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modification of Rutynowski by Marshall does not amount to a mere design choice and is, in fact, ineffective, inoperable, and negated by the teachings of Rutynowski.

Even if the modification were proper (which Applicants submit that it is not), the combination of Rutynowski and Marshall still fails to teach or suggest the patentable feature discussed above, wherein the puncture force is adjusted without adjusting the drive spring. Indeed, that patentable feature enables the device of the present invention to adjust puncture force without risking the premature breaking of the wings 12, which the combination of Rutynowski and Marshall fails to address, as described above.

Furthermore, as benefits over Marshall and other prior art, the present invention prolongs the life span and operational reliability of the puncturing device by keeping the initial biasing tension of the drive spring constant and small regardless of the set puncturing force, to maintain small forces on the drive spring, piston, and breakable wings. In addition to increasing life span and reliability, those small forces also improve the safety of the device. When a technician adjusts the puncturing force as appropriate, the initial bias force of the drive spring remains constant and small during, for example, transportation and storage of the device, until it is ready for use on a patient. During that intermediate time between adjustment and use, maintaining the small and constant force reduces the danger of unintended deflection or breaking of the wings 12, of self activation of the device, or of its improper activation after intended activation, thereby providing a safer device for the patient.

As a further benefit, the construction of the device of the present invention has few components, is simple and inexpensive, which can be important for mass medical use.

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Thus, contrary to the Examiner's assertion, the current claims do, in fact, recite the patentable feature of adjusting puncture force without adjusting the drive spring, which the prior art fails to teach or suggest. Accordingly, Applicants respectfully submit that independent claims 3, 4, and 12 are patentable over the prior art. In addition, Applicants respectfully submit that dependent claims 8, 10, and 13-19 are also patentable due at least to their dependence on an allowable base claim and for the additional features recited therein.

In view of the foregoing, all of the claims in this case are believed to be in condition for allowance. Should the Examiner have any questions or determine that any further action is desirable to place this application in even better condition for issue, the Examiner is encouraged to telephone Applicants' undersigned representative at the number listed below.

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